

MAR 11 1992

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions:

Common or Usual Name: Steerable Guidewire

Proprietary Name: ESSENCE™ Guidewire

II. Name of Predicate Devices

Cordis Endovascular Systems, Inc. Instinct® Steerable Guidewire (K930982)

Cordis Corporation Reflex Steerable Guidewire (K905432)

Target Therapeutics Dasher Guidewire (K914030)

III. Classification:

Class II

IV. Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The ESSENCE™ Guidewires are intended for the introduction and positioning of catheters and interventional devices within the peripheral, coronary and neurovascular systems. The guidewires have a soft, flexible tip and may be used with intravascular devices what are indicated for use with such guidewires.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the Cordis Endovascular Systems, Inc. ESSENCE™ Guidewire.

VII. Summary of Substantial Equivalence

The ESSENCE™ Guidewires are similar in its basic design, construction, indication for use and performance characteristics to other commercially available steerable guidewires.